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New Jersey State Board
of Medical Examiners
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Re: Affiliation with and Registration of Surgical Practices

Dear Dr. [REDACTED]

On your last biennial renewal application you identified that you were affiliated with a surgical practice. By this letter, we want to alert you to certain obligations that you and the entity at which you practice may have as a result of that affiliation.

Registration with the Department of Health

Pursuant to P.L. 2009, c. 24, all surgical practices then in operation were required to register with the Department of Health by April 16, 2012, N.J.A.C. 8:43C-1.4(c). The Department of Health will continue to issue registrations for existing surgical practices only until October 31, 2012. The application must be complete by that date in order for a registration certificate to be issued. The registration date on the registration certificate will be the date the application is complete. The Department of Health will not issue registration certificates to existing surgical practices after this date. Surgical practices not yet open that met the statutory filing deadline in N.J.S.A. 26:2H-12 must register with the Department of Health prior to offering services.

For purposes of this requirement, a surgical practice has the following characteristics:

1. No more than one operating room that is:
 - i. Specially equipped to perform surgery; **and**
 - ii. Designed and constructed to accommodate invasive diagnostic and surgical procedures;
2. Has one or more post-anesthesia care units or a dedicated recovery area, which includes the operating room if used for recovery, where the patient may be closely monitored and observed until discharged; and
3. Was established by a physician, physician professional association surgical practice or other professional practice form that is recognized in regulation by the Board of Medical Examiners solely for the physician's, association's or other professional practice entity's private medical practice.

At present, the Department of Health does not consider the following practice locations with the following characteristics to be surgical practices, and thus registration is not required:

1. A procedure room used for endoscopies and cystoscopies that has a sink in the room. This room cannot be used for surgery due to sterility issues; or
2. A room used only for pain management injections.

Please be aware that pursuant to N.J.S.A. 26:2H-12, a new surgical practice, not in existence when the statute was enacted, will not be recognized and is not permitted, unless building plans were submitted to the municipality in which the surgical practice is located, prior to September 19, 2009. This is an outright ban on new surgical practices. The statute also does not permit existing surgical practices to make changes in their current operating room that would change the scope of services. For example, if an existing surgical practice currently only performs procedures using IV or conscious sedation in a surgical practice, it cannot begin offering general anesthesia. If you are currently doing procedures under local anesthesia, unless you submitted building plans prior to the statutory deadline, you cannot become a surgical practice because of the statutory ban on new surgical practices.

Although April 16, 2012 was the deadline, if you conclude that the entity with which you are affiliated needs to be registered, that entity should submit the application immediately and have a complete application to the Department of Health no later than October 31, 2012. Information on the registration process and the application is available online at:

http://nj.gov/health/healthfacilities/documents/surgical_practices_notification.pdf

Please contact Eugene Brenycz, Regulatory Officer, Department of Health, Office of Certificate of Need and Healthcare Facility Licensure at (609) 292-5960, with any questions regarding the registration process.

Surgical and Anesthesia Standards

Even though your practice may not be required to register with the Department of Health because of its physical characteristics, you should be aware that there are regulations promulgated by the Board of Medical Examiners that extend to all physicians performing surgery, special procedures and/or administering or supervising the administration of anesthesia in an office. You are encouraged to become familiar with these standards, all of which are available through the Board of Medical Examiners website at <http://www.state.nj.us/lps/ca/bme/>.

We would like to highlight some of the requirements here:

Alternative Privileges

If you do not have any hospital privileges to perform the procedures or administer or supervise the administration of anesthesia, you must obtain Alternative Privileges pursuant to N.J.A.C. 13:35-4A.12. A description of these privileges and information on how to apply can be found at www.state.nj.us/lps/ca/bme/privilege/altpriv.htm.

Duty to Report Complications

You also have obligations pursuant to N.J.A.C. 13:35-4A.5 to report incidents related to surgery, special procedures, or anesthesia in your office. The rule states:

Any incident related to surgery, special procedures or the administration of anesthesia within the office which results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication or untoward event as defined in

N.J.A.C. 13:35-4A.3, shall be reported to the Executive Director of the Board within seven days, in writing and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. 45:9-19.3.

And "complications" are defined in N.J.A.C. 13:35-4A.3 as follows:

"Complications" means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office setting including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usually outcome of the procedure.

(A form for reporting can be found at www.state.nj.us/lps/ca/bme/reportob/obligations.htm.)


Correction or Changes in Circumstances

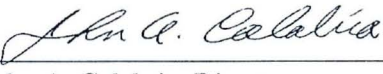
Upon reviewing this notice, if you believe that you have erroneously answered the question concerning your affiliation with a surgical practice, as the Department of Health has defined it, please notify the Board immediately by sending an email, within 10 days of receipt of this letter to: surgical@dca.lps.state.nj.us

Thank you for your cooperation and attention to this matter.

Very truly yours,
STATE BOARD OF MEDICAL EXAMINERS

STATE DEPARTMENT OF HEALTH

By: 
William V. Roeder, Executive Director

By: 
John A. Calabria, Director
Office of Certificate of Need and
Healthcare Facility Licensure